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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,648	10/17/2000	Shalaby Wahba Shalaby	00537-165002	9033

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/600,648

**Applicant(s)**

SHALABY, SHALABY WAHBA

**Examiner**

David M. Naff

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/3/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/3/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

An amendment of 9/30/04 amended claims 1-13, 22-34, 38, 40, 42, 43 and 46, and added new claims 47 and 48.

Claims examined on the merits are 1-48, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not recite "intermediate subsurface" recited in line 4 of claim 1. While a subsurface is referred to at page 14, line 6, there is no disclosure of an intermediate subsurface. This recitation results in a different concept of the invention than originally disclosed.

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***Claim Rejections - 35 USC § 112***

Claims 1-48 are rejected under 35 U.S.C. 112, second paragraph,  
as being indefinite for failing to particularly point out and  
distinctly claim the subject matter which applicant regards as the  
5 invention.

In line 4 of claim 1, "immediate subsurface" is uncertain as to  
meaning and scope. Being "immediate" is relative and subjective, and  
dependent on individual interpretation.

***Claim Rejections - 35 USC § 103***

10 Claims 1-11, 22, 23, 26-33 and 47 rejected under 35 U.S.C. 103(a)  
as being unpatentable over Shalaby et al (5,672,659) or Ignatious et  
al (WO 97/39738) in view of Shalaby (5,612,052) and Chesterfield et al  
(5,366,756) for reasons set forth in the previous office action of  
4/7/04 and for reasons herein.

15 The claims are drawn to a bound microparticle comprising an  
absorbable heterochain polymer core and one or more peptides and/or  
proteins ionically immobilized on the surface and immediate subsurface  
of a core.

20 Shalaby et al ('659) and Ignatious et al disclose a composition  
containing a carboxyl group-containing polymer that can be a  
heterochain polymer ionically conjugated (col 2, line 65 of Shalaby et  
al and page 1, line 23 of Ignatious et al) with a bioactive  
polypeptide or a drug that is a polypeptide. The conjugate may be  
formed into microparticles. The conjugate is formed by combining a

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solution of the polymer with a solution of the polypeptide. See cols 2 and 3 of Shalaby et al and pages 4-9 of Ignatious et al.

Shalaby et al ('052) discloses coating microparticles with a drug to provide controlled release of the drug (col 7, lines 30-33).

5 Chesterfield et al disclose polymer particles coated with a tissue growth promoter and if desired a therapeutic agent for implanting to repair tissue (cols 1-3).

The present invention differ from Shalaby et al ('659) and Ignatious et al in that in the claims the polymer is formed into a  
10 microparticle and the polypeptide or protein is immobilized on the microparticle, whereas Shalaby et al and Ignatious et al form the conjugate by combining solutions of the polymer and polypeptide or protein and form a microparticle of the conjugate.

It would have been obvious to form the polymer of Shalaby et al  
15 ('659) or Ignatious et al into a microparticle prior to conjugating with the polypeptide or protein as suggested by Shalaby et al ('052) and Chesterfield et al forming a polymer microparticle and immobilizing a drug and/or growth promoter on the microparticle. Forming the microparticle before binding the protein or polypeptide  
20 would have been expected to provide the protein or polypeptide on the surface of the microparticle and make it more readily available. When coating the microparticle as suggested by Shalaby ('052) and Chesterfield et al, the polypeptide will inherently be on the surface and immediate subsurface of the microparticle. The conditions of

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dependent claims would have been matters of obvious choice in view of conditions disclosed by the references.

***Response to Arguments***

It is granted as urged by applicant that Shalaby et al and Ignatious et al provide the peptide throughout the particle. However, when following the teachings of Shalaby ('052) and Chesterfield et al to apply the peptide after forming the microparticle, the peptide will inherently be on the surface and an immediate subsurface. While Shalaby ('052) may not disclose an absorbable polyester and Chesterfield et al may not disclose ionic immobilization, the polyester is suggested by Shalaby et al ('659) or Ignatious et al, and ionic immobilizing is suggested by Shalaby et al ('659) or Ignatious et al and the '052 patent. The references are applied in combination and must be considered together as a whole and not each alone. Moreover, the invention as broadly claimed does not require a polyester as the polymer. There is clearly sufficient motivation in the references to make the present invention prima facie obvious.

***Claim Rejections - 35 USC § 103***

Claims 12-21, 24, 25, 34-46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-11, 22, 23, 26-33 and 47 above, and further in view of Auer et al (WO 92/11844) and Demian et al (5,795,922) for reasons in the previous office action.

The claims require the bound microparticle containing the immobilized protein or polypeptide to be encased.

Auer et al disclose forming a complex of a protein pharmaceutical agent and a polycationic reagent, and encapsulating the complex in a microsphere (pages 4-9) to provide sustained release of the protein.

Demian et al disclose microencapsulating radiopacifier particles to prevent agglomerating (col 3).

When modifying Shalaby et al ('659) or Ignatious et al by forming the polymer into a microparticle before binding the protein or polypeptide as set form above, it would have been obvious to encapsulate the protein or polypeptide-containing microparticle as suggested Auer et al to provide sustained release and as suggested by Demian et al to prevent agglomerating.

### ***Response to Arguments***

Applicant urges that it would not have been apparent from Auer et al that the peptide can be immobilized on the surface of the microparticle since Auer et al complex a peptide with a polycation. However, Auer et al is not relied on for immobilizing the peptide on the surface of a microparticle since this is suggested by the references applied in the rejection above. Encapsulating as taught by Auer et al and Demian et al to prevent agglomerating would have been obvious when a peptide is on the surface of a polypeptide since a microparticle containing a surface immobilized peptide would have been expected to be capable of agglomerating.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

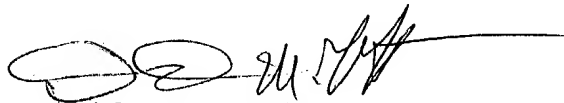
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
12/27/04